FEB 2 1999

510(k) Summary
for
XiScan Expert Imaging Systems

K984406

1. SPONSOR

XiTec, Inc.
4 New Park Road
East Windsor, CT 06088

Contact Person: Steven Hanright
Telephone: (860) 627-7500

Date Prepared: December 8, 1998

2. DEVICE NAME

Proprietary Name:	XiScan Expert Imaging Systems
Common/Usual Name:	Mini c-arm systems
Classification Name:	Image-intensified fluoroscopic X-ray systems

3. PREDICATE DEVICES

Fluoroscan Premier
Fluoroscan OfficeMate
OEC Mini 6600 Digital Mobile C-arm

4. DEVICE DESCRIPTION

The XiScan Expert Imaging Systems are compact, mobile, mini c-arm systems specifically designed for fluoroscopic imaging of patient extremities. Two versions are available: the XiScan Office Expert and the XiScan Surgical Expert. The systems can be operated in either manual or automatic exposure rate control (AERC) modes, with options of reduced radiation LOW DOSE and high resolution STANDARD DOSE when using AERC. Both systems offer a range of options for image manipulations. The Surgical Expert also features a remote, hand-held keypad to manage on-screen patient information and image storage.

5. INTENDED USE

The XiScan Expert Imaging Systems are intended for fluoroscopic imaging of patient extremities.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The XiScan Expert Imaging Systems have the same intended use, and similar technical specifications, as compared to the predicate devices. All devices are mini c-arm systems with similar technique factors, SIDs, field-of-view sizes, and image enhancement options. A bench test comparison of the devices confirmed that the patient X-ray exposure rates for imaging various anatomies are similar. Based on these comparisons, the XiScan Expert Imaging Systems are substantially equivalent to the Fluoroscan and OEC mini c-arm systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

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Sheila M. Hemeon-Heyer, Esq., RAC
Senior Staff Consultant
c/o Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K984406
XiScan Office Expert Imaging System
XiScan Surgical Expert Imaging System
Dated: December 8, 1998
Received: December 9, 1998
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA
21 CFR 892.1720/Procode: 90 IZL

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984406

Device Name: XiScan Expert Imaging Systems

Indications For Use:

The XiScan Expert Imaging Systems are intended for fluoroscopic imaging of patient extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984406

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)